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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known Application Number 10/669,251 Filing Date September 25, 2003 First Named Inventor Leland SHAPIRO Art Unit 3736 Examiner Name Not Yet Assigned Attorney Docket Number 330310.00102

			U. S. PATENT	DOCUMENTS	
Examiner initials*	Cite No.1	Document Number Number-Kind Code ^{2 (Jumer)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
KW	1	^{US-} 4,021,472 A	05/1977	Fujii et al.	
KW	2	^{US-} 4,051,842 A	10/1977	Hazel et al.	
KW	3	^{US-} 4,140,122 A	02/1979	Kuhl et al.	
KW	4	^{US-} 4,224,342 A	09/1980	Fujii et al.	
_KW	5	^{US-} 4,283,418 A	08/1981	Fuji et al.	
KW	6	^{US-} 4,310,533 A	01/1982	Uegai et al.	
	7	^{US-} 4,383,529 A	05/1983	Webster	
KW	8	^{US-} 4,629,567 A	12/1986	Bollen et al.	
KW	9	^{US-} 4,657,763 A	04/1987	Finkelstein	
KW	10	^{US-} 4,668,504 A	05/1987	Kahan et al.	
KW	11	^{US-} 4,711,848 A	12/1987	Insley et al.	
KW	12	^{US-} 4,713,224 A	12/1987	Tamhankar et al.	
KW	13	^{US-} 4,732,973 A	03/1988	Barr et al.	
KW	14	^{US-} 4,760,130 A	07/1988	Thompson et al.	
KW	15	US- 4,788,603 A	11/1988	Fujimura et al.	
К	_W 16	^{US-} 4,829,052 A	05/1989	Glover et al.	
KW		^{US-} 4,839,283 A	06/1989	Kawasaki et al.	
KW	18	^{US-} 4,843,094 A	06/1989	lmaki et al.	
KWKW	19	^{US-} 4,889,723 A	12/1989	Kim et al.	

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	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	Γ				
		Country Code ³ Number ⁴ Kind Code ⁴ (# known)	MM-DD-YYYY		Or Relevant Figures Appear	۲				
KW	20	WO 94/07525	04/1994							
KW	21	WO 95/28422	10/1995							
TZTA	22	WO 95/34538	12/1995							
KW	23	WO 96/12021	04/1996							
KW	24	WO 96/14067	05/1996							
	25	WO 97/03679	02/1997							

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			U.S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.	Document Number Number-Kind Code ^{2 (/ kcowr)}	Publication Date MM-DD-YYYY	Name of Patentae or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
KW	26	^{US-} 4,931,279 A	06/1990	Bawa et al.	
	27	^{US-} 4,963,654 A	10/1990	Katunuma	
	28	^{US-} 5,004,612 A	04/1991	Kim et al.	
\neg	29	^{US-} 5,077,428 A	12/1991	Imaki et al.	
	30	^{US-} 5,110,602 A	05/1992	Kim et al.	
1	31	^{US-} 5,157,019 A	10/1992	Glover et al.	
T	32	^{US-} 5,166,134 A	11/1992	Lezdey et al.	
	33	^{US-} 5,175,253 A	12/1992	Fallon et al.	
1	34	^{US-} 5,214,191 A	05/1993	Kirschenheuter et al	
7	35	^{US-} 5,216,022 A	06/1993	Oleksyszyn et al.	
1	36	^{US-} 5,240,956 A	08/1993	Kirschenheuter et al	
	37	^{US-} 5,247,084 A	09/1993	Imaki et al.	
	38	^{US-} 5,399,346 A	03/1995	Anderson et al.	
	39	^{US-} 5,416,191	05/1995	Cheronis et al.	
	40	^{US-} 5,420,110 A	05/1995	Miller et al.	
T	41	^{US-} 5,432,178 A	07/1995	Nakai et al.	
1	42	^{US-} 5,470,970 A	11/1995	Saeger et al.	
V	43	^{US-} 5,476,995 A	12/1995	Clark et al.	
(0)	44	^{US-} 5,478,727 A	12/1995	Roizman et al.	

	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages					
		Country Code ³ Number ⁴ Kind Code ⁸ (# known)	MM-DD-YYYY		Or Relevant Figures Appear	T°				
Cerl	45	WO 97/09346	03/1997							
	46	WO 97/09347	03/1997							
	47	WO 97/10222	03/1997							
	48	WO 97/10231	03/1997							
1	49	WO 97/21690	06/1997			L				
200	50	WO 97/24339	07/1997							

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Signature	/Kevin Weddington/ (02/15/2006)	Considered	
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	NFORMATIC	M DISC	LOCUDE	Filing Date	September 25, 2003	
_				First Named Inventor	Leland SHAPIRO	
	STATEMENT			Art Unit	3736	
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				DOCUMENTS	
Examiner Initials*	Cita No.	Document Number Number-Kind Code ^{2 (1 travel)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Peges, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
Ken	51	^{US-} 5,486,470 A	01/1996	Darke et al.	
+ 00	52	^{US-} 5,489,593 A	02/1996	Palmer et al.	
	53	US- 5,504,094 A	04/1996	Nakane et al.	
	54	^{US-} 5,514,653 A	05/1996	Perlmutter	
	55	^{US-} 5,514,713 A	05/1996	Nakai et al.	
	56	^{US-} 5,529,920 A	06/1996	Cole et al.	
	57	^{US-} 5,532,215 A	07/1996	Lezdey et al.	
	58	US- 5,565,334 A	10/1996	Kufe et al.	
	59	^{US-} 5,567,682 A	10/1996	Pert	
\neg	60	^{US-} 5,593,858 A	01/1997	Fleer et al.	
T	61	^{US-} 5,604,201 A	02/1997	Thomas et al.	
	62	^{US-} 5,610,140 A	03/1997	Goodfellow et al.	
	63	^{US-} 5,610,285 A	03/1997	Lebing et al.	
	64	US- 5,614,555 A	03/1997	Nakai et al.	
	65	^{US-} 5,616,693 A	04/1997	Hwang et al.	
	66	^{US-} 5,618,792 A	04/1997	Gyorkos et al.	
	67	^{US-} 5,622,984 A	04/1997	Nakai et al.	
	68	^{US-} 5,635,593 A	06/1997	Cheronis et al.	
(6)	69	^{US-} 5,641,670 A	06/1997	Treco et al.	

	FOREIGN PATENT DOCUMENTS								
	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages				
		Country Code ³ "Number ⁴ "Kind Code ³ (#known)	MM-DD-YYYY		Or Relevant Figures Appear	Ľ			
10.7	70	WO 97/31937	09/1997						
7	71	WO 97/33996	09/1997						
	72	WO 97/37969	10/1997			L			
	73	WO 97/45402	12/1997						
. \	74	WO 97/48706	12/1997						
TO,	75	WO 97/49679	12/1997			Г			

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				First Named Inventor	Leland SHAPIRO	
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			U. S. PATENT	T DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (Florate)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear
W	76	^{US-} 5,663,416 A	09/1997	Kirschenheuter et al	
T	77	^{US-} 5,665,589 A	09/1997	Harris et al.	
1	78	^{US-} 5,700,779 A	12/1997	Goodfellow et al.	
1	79	^{US-} 5,710,026 A	01/1998	Sprecher	
1	80	^{US-} 5,712,117 A	01/1998	Sprecher	
1	81	^{US-} 5,747,645 A	05/1998	Sprecher	
	82	^{US-} 5,750,506 A	05/1998	Goodfellow et al.	
	83	^{US-} 5,759,548 A	06/1998	Bathurst et al.	
	84	^{US-} 5,780,009 A	07/1998	Karatzas et al.	
	85	^{US-} 5,798,442 A	08/1998	Gallant et al.	
	86	^{US-} 5,801,148 A	09/1998	Gyorkos et al.	
	87	^{US-} 5,804,594 A	09/1998	Murad	
	88	^{US-} 5,807,829 A	09/1998	Gyorkos et al.	
1	89	^{US-} 5,811,241 A	09/1998	Goodfellow et al.	
1	90	US-5,817,484 A	10/1998	Yu et al.	
	91	US-5,834,431 A	11/1998	Stewart et al.	
7	92	^{US-} 5,843,900 A	12/1998	Cheronis et al.	
	93	^{US-} 5,849,863 A	12/1998	Stewart et al.	
10	94	^{US-} 5,861,299 A	01/1999	Archibald et al.	

		FORE	IGN PATENT DOCU	MENTS		•
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ "Number ⁴ "Kind Code ⁵ (If known)	MM-DD-YYYY		Or Relevant Figures Appear	T⁰
ia	95	WO 98/06417	02/1998			
	96	WO 98/09206	03/1998			
	97	WO 98/20034	05/1998			
	98	WO 98/21186	05/1998			
A	99	WO 98/22098	05/1998			
W	100	WO 98/22619	05/1998			

Examiner Signature	/Kevin Weddington/	(02/15/2006)	Date Considered	

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Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where	
Initials*	tials* No.' Number-Kind Code ² (/treen)		M.M-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
W	101	^{US-} 5,861,380 A	01/1999	Gyorkos et al.	•	
	102	^{US-} 5,863,899 A	01/1999	Cheronis et al.		
	103	^{US-} 5,869,455 A	02/1999	Gyorkos et al.		
T	104	^{US-} 5,874,424 A	02/1999	Batchelor et al.		
1	105	^{US-} 5,874,585 A	02/1999	Gyorkos et al.		
	106		04/1999	Gyorkos et al.		
T	107	^{US-} 5,914,342 A	06/1999	Maurer et al.		
1	108	^{US-} 6,127,356 A	10/2000	Crapo et al.	***	
1	109	^{US-} 6,140,116 A	10/2000	Dinsmore et al.		
T	110	^{US-} 6,235,714 B1	05/2001	Paul et al.		
T	111	^{US-} 6,323,219 B1	11/2001	Costanzo		
	224	^{US-} 5,281,617 A	01/1994	Kirschenheuter et al		
-	225	410	05/1994	Kirschenheuter et al		
1(2.	226	^{US-} 5,376,655 A	12/1994	lmaki et al.		
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		FORE	IGN PATENT DOCU	MENTS			
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		Country Code ³ Number ⁴ 'Kind Code ⁸ (If known)	MM-DD-YYYY		Or Relevant Figures Appear	T	
14	112	WO 98/23565	06/1998				
	113	WO 98/24806	06/1998				
	114	WO 98/46597	10/1998				
	115	WO 98/49190	11/1998				
	116	WO 98/50342	11/1998				
एप	117	WO 98/50420	11/1998				

Examiner Signature	/Kevin Weddington/ (02/15/2006)	Date Considered	

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Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (^{J.L.co7})	Publication Date MM-OD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Linas, Where Relevant Passages or Relevant Figures Appear
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160	118	WO 98/56821	12/1998			
ĺ	119	WO 97/41231	08/1999			
	120	WO 99/43308	09/1999			
10.	121	WO 00/52034	09/2000			

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STA	TEMENT	BY A	PPLICANT	First Named Inventor	Leland SHAPIRO
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Sheet	7	of	17	Attorney Docket Number	330310.00102

		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials* Cite No.¹		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					
		Aoki H, Akaike T, Abe K, Kuroda M, Arai S, Okamura R, Negi A, Maeda H. Antiviral effect of oryzacystatin, a proteinase inhibitor in rice, against herpes simplex virus type I in vitro and in vivo. Antimicrob Agents Chemother Apr. 1995; 39(4):846-9.					
7	123	Auerswald et al., "Recombinant leech-derived tryptase inhibitor: construction, production, protein chemical characterization and inhibition of HiV-1 replication", Biol Chem Hoppe Seyler, 375(10):695-703 (1994).					
	124	Avril LE, Di Martino-Ferrer M, Barin F, Gauthier F., "Interaction between a membrane-associated serine proteinase of U-937 monocytes and peptides from the V3 loop of the human immunodeficiency virus type I (HIV-1) gp120 envelope glycoprotein", FEBS Lett, 317(1-2):167-72 (Feb. 8, 1993).					
	125	Beal, M.F., "Mitochondria, Free Radicals, and Neurodegeneration", Curr. Opin. Neurobiol., 1996, 6, 661-666.					
	126	Bjorck L, Grubb A, Kjellen L. Cystatin C, a human proteinase inhibitor, blocks replication of herpes simplex virus. J Virol Feb. 1990;64(2):941-3.					
	127	Carroccio A, Fontana M, Spagnuolo MI, Zuin G, Montalto G, Canani RB, Verghi F, Di Martino D, Bastoni K, Buffardi F, Guarino A., "Pancreatic dysfunction and its association with fat malabsorption in HIV infected children", Gut, 43(4):558-63 (Oct. 1998).					
	128	Cox et al., "Synergistic combinations and peptides in the inhibition of human immunodeficiency virus", Adv Enzyme Regul, 31:85-97 (1991).					
	129	Deigner, H.P. and R. Kinscherf, "Modulating Apoptosis: Current Applications and Prospects for Future Drug Development", Curr Med Chem 1999, 6, 399-414.					
	130	Dilanni CL, Drier, DA, Deckman IC, McCann PJ 3d, Liu F, Roizinen B, Colonno RJ, Cordingley MG. Identification of the herpes simplex virus-I protease cleavage sites by direct sequence analysis of autoproteolytic cleavage products. Biol Chem Jan. 25, 1993;268(3):2048-51.					
16	131	Dilanni CL, Stevens JT, Bolgar M, O'Boyle DR 2nd, Weinheimer SP, Colonno RJ. Identification of the serine residue at the active site of the herpes simplex virus type 1 protease. J Blol Chem Apr. 29, 1994;269(17):12672-6.					

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Signature	/Kevin Weddington/ (02/15/2006)	Considered	<u> </u>
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STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Leland SHAPIRO	
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Sheet	8	of	17	Attorney Docket Number	330310.00102	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
Ken	132	Flaitz CM, Hicks MJ. "Molecular piracy: the viral link to carcinogenesis." Oral Oncol Nov. 1998;34(6):448-53.	
	133	Griffin, William C., "Calculation of HLB Values of Non-Ionic Sufactants", [H. L. BThe Hydrophilic-Lipophilic Balance], J. Soc. Cos. Met. Chem., vol. 5, p. 249 (1954).	
	134	Holwerda BC. Herpesvirus proteases: targets for novel antiviral drugs. Antiviral Res Jun. 1997;35(1):1-21.	
	135	Inocencio et al., *Endoprotease activities other than furin and PACE4 with a role in processing of HIV-I gp160 glycoproteins in CHO-K1 cells*, J Biol Chem, 272(2):1344-8 (1997).	
	136	Jabs, Thorsten, "Reactive Oxygen Intermediates as Mediators of Programmed Cell Death in Plants and Animals", Biochem Pharmacol 1999, 57, 231-245.	
	137	Kaufmann, Scott H., Serge Desnoyers, Yvonne Ottavlano, Nancy E. Davidson, and Guy G. Poirler, "Specific Proteolytic Cleavage of Poly(ADP-ribose) Polymerase: An Early Marker of Chemotherapy-induced Apoptosis", Cancer Res 1993, 53, 3976.	
	138	Kidd, Vincent J., Proteolytic Activities That Mediate Apoptosis, Annu Rev Physiol, 1998, 60, 533.	
	139	Kido H, Niwa Y, Beppu Y, Towatari T. Cellular proteases involved in the pathogenicity of enveloped animal viruses, human immunodeficiency virus, influenza virus A and Sendai virus. Adv Enzyme Regul 1996;36-325-47.	
	140	Best, P.J.M., et al., Arterioscler Thromb Vasc Biol 1999, 19, 14.	
W	141	Lomas DA, Elliott PR, Carrell RW. Commercial plasma alphal-antitrypsin (Prolastin) contains a confornationally inactive, latent component. Eur. Respir J Mar. 1997;10(3):672-5	

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la	142	Meylan et al., "HIV infectivity is not augmented by treatment with trypsin, Factor Xa or human mast-cell tryptase", AIDS, 6(1):128-30 (1992).	
	143	Miranda et al., "Isolation of the human PC6 gene encoding the putative host protease for HIV-1 gp160 processing in CD4+ T lymphocytes", Proc Natl Acad Sci U S A, 93(15):7695-7700) (1996).	
	144	Molle W. et al. in J Immunol 1997, 159, 3555.	
	145	Morel, J. B. and Dangle, J.L., Cell Death Differ 1997, 4, 67 1.	
	146	Ohnishi et al., "A furin-defective cell line is able to process correctly the gp160 of human immunodeficiency virus type I", J Virol, 68(6):4075-99 (1994).	
	147	Okumura et al., "The extracellular processing of HIV-1 envelope glycoprotein gp160 by human plasmin", FEBS Lett, 442(1):39-42 (1998).	
	148	Pellegrini A, Thomas U, Franchini M, Stockli M, Klauser S, Hunziker P, von Fellenberg R. Identification of an aprotinin antiviral domain. FEBS Lett May 16, 1994;344(2-3):261-5.	
	149	Schwartz, et al., "Antiviral activity of the proteasome on incoming human immunodeficiency virus type I", J Virol, 72(5):3845-50) (1998).	
	150	Sichko ZhV, Koslova OL. Experience in treating herpetic infection with trypsin [Article in Russian]. Vrach Delo Mar. 1991;86-9.	
	151	Szeghy G, Kenyeres B. On the therapy of herpes simplex keratitis with heparin and trypsin. [Article in German] Klin Monatsbl Augenheilkd 1968; 153(6):827-30.	

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Signature	/Kevin Weddington/ (02/15/2006)	Considered	

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ll	U	152	Cilberto et al., 1985, Cell, 41:531-540.	
		153	Dery O. and Bunnett, N.W. Biochem Soc Trans 1999, 27, 246-254.	
		154	Altieri, D.C. J Leukoc Biol 1995, 58, 120-127.	
		155	Dery, O. et al. Am J Physiol 1998, 274, C1429-C1452.	
		156	Patel R. P., et al. in Biochim Biophys Acta 1999, 1411, 385-400.	
		157	Lowenstein, C. J. and Snyder, S. H. in Cell 1992, 70, 705-707.	
		158	Beck, K.F. et al. in J Exp Biol 1999, 202, 645-53.	
		159	Kirkeboen, K.A. and Strand, O.A. in Acta Anaesthesiol Scand 1999, 43, 275.	
		160	Wood, E. R. et al. in Biochem Biophys Res Commun 1993, 191, 767-74.	
(ζω	161	Lowenstein C. J. et al. in Proc. Natl. Acad. Sci. USA, 1993, 90, 9730.	

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STA	TEMENT	BY A	PPLICANT	First Named Inventor	Leland SHAPIRO	
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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
10	162	Nathan, C. in FASEB J. 1992, 6, 3501.	
	163	Rehman, A. et al. in Br J Pharmacol, 1997, 122, 1702.	
	164	Pryor, W. A. et al., in Chem Biol Interact 1985, 54, 171.	
	165	Van Molle W. et al. in J Immunol 1997, 159, 3555.	
	166 Bratt, J. and Palmblad, J. in J Immunol 1997, 159, 812.		
	167	Ding, A. et al., in J. Immunol. 1990, 145, 940.	
	167	Heck, D. E. et al., in J. Biol. Chem. 1990, 267, 21277.	
	169	McCall, T.B. et al., in Biochem. Biophys. Res. Commun. 1992, 186, 680.	
	170	Punjabi, C. J. et al., in J. Immunol. 1992, 149, 2179.	
l l	171	Goureau, O. et al., in Proc. Natl. Acad. Sci. U.S.A. 1993, 90, 4276.	

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		NON PATENT LITERATURE DOCUMENTS	
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14	172	Schini et al. in Circ Res 1994, 74, 24.	
	173	Meki, A. R. et al. in Toxicon 1998, 36, 18519.	
	174	Popko B. and Baerwald, K. D. in Neurochem Res 1999, 24, 331.	
	175	Smith, M. E. in Neurochem Res 1999, 24, 261.	
	176	Sambrook, Fristsch & Maniatis, Molecular Cloning: A Laboratory Manual, Second Edition 1989, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y.	
	177	Remington's Pharmaceutical Sciences, 1990, p. 1519-1675, Gennaro, A.R., ed., Mack Publishing Company, Easton, PA.	
	178	Langer, R., Nature, 1998, 392, 5.	
	179	Budavari, Susan (Editor), "The Merck Index", An Encyclopedia of Chemicals, Drugs, and Biologicals; Merck & Co., Inc., 11th edition.	
	180	Merrifield, R.B., "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide", 1963, J. Am. Chem. Soc., (85):2149.	
lu	181	Animal Cell Culture, R.I. Freshney, ed. 1986, IRL Press, Oxford.	

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Under the Processor's Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 10/669,251 INFORMATION DISCLOSURE Filing Date September 25, 2003 STATEMENT BY APPLICANT **First Named Inventor** Leland SHAPIRO Art Unit 3736 (Uso as many sheets as necessary) **Examiner Name** Not Yet Assigned **Attorney Docket Number** Sheet 17 330310.00102 13 of

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1 Gaz	182	Scharpe et al., "Protease and their inhibitors: today and tomorrow", 1991, Biochimie, 73(1):121-126.			
	183	Kido et al., "A novel membrane-bound serine esterase in human T4+ lymphocytes immunologically reactive with antibody inhibiting syncytia induced by HIV-1. Purification and characterization", J Biol Chem., 1990, 265(35):21979-85.			
	184	Brinkman et al., "Inhibition of tryptase TL2 from human T4+ lymphocytes and inhibition of HIV-1 replication of H9 cells by recombinant aprotinin and bikunin homologues", 1997, J. Protein Chem., 16(6)(:651-660.			
	Auerswald et al., "K15R M52E) aprotinin is a weak Kunitz-type inhibitor of HIV-1 replication in H9 cells" Biomed Biochim Acta, 1991, 50(4-6):697-700.				
	Kamoshita et al., "Calcium requirement and inhibitor spectrum for intracellular HIV type 1 gp160 processing in cultured HeLa cells and CD4+ tymphocytes: similarity to those of viral envelope glycoprotein maturase", J Biochem. Tokyo, 1995, 117(6):1244-53.				
	187	Koito et al., "A neutralizing epitope of human immunodeficiency virus type 1 has homologous amino acid sequence with the active site of inter-alpha-trypsin inhibitor", 1989, Int Immunol, 1(6):613-8.			
	188	McNeely et al., "Secretory leukocyte protease inhibitor: a human saliva protein exhibiting anti-human immunodeficiency virus 1 activity in vitro", 1995, J Clin Invest, 96(1):456-64.			
	189	Hallenberger et al., "Inhibition of furin-mediated cleavage activation of HIV-1 glycoprotein gp160", 1992, Nature, 360(6402):358-61.			
	190	Vollenweider, et al., 'Comparative cellular processing of the human immunodeficiency virus (HIV-1) envelope glycoprotein gp160 by the mammalian subtilisin/kexin-like convertases', 1996, Biochem. J.;314 (Pt2):521-32.			
1	191	Anderson et al., "Inhibition of HIV-1 gp160-dependent membrane fusion by a furin-directed alpha 1-antitrypsin variant", 1993, J Biol Chem, 268(33):24887-91.			

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INFO	DRMATION	I DIS	CLOSURE	Filing Date	September 25, 2003	
STA	TEMENT	BY A	PPLICANT	First Named Inventor	Leland SHAPIRO	
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Sheet	14	of	17	Attorney Docket Number	330310.00102	

	T 61:	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
Lh	192	Decroly, et al., "Identification of the paired basic convertases implicated in HIV gp160 processing based on in vitro assays and expression in CD4(+) cell lines", 1996, J Biol Chem, 271(48):30442-50.	
	193	Moulard, et al., "Kex2p: a model for cellular endoprotease processing human immunodeficiency virus type 1 envelope glycoprotein precursor", Eur J Biochem, 1994, 225(2):565-72.	
	194	Avril, et al., "Identification of the U-937 membrane-associated proteinase interacting with the V3 loop of HIV-1 gp120 as cathespin G", FEBS Lett, 1994, 345(1):81-6.	
	195	Harvima et al., "Separation and partial characterization of proteinases with substrate specificity for basic amino acids from human MOLT-4 T lymphocytes: identification of those inhibited by variable-loop-V3 peptides of HIV-1 (human immunodeficiency virus-1) envelope glycoprotein*, 1993, Biochem J, 292 (Pt 3):711-8.	
	196	Bourinbaiar, et al., "Acrosin inhibitor, 4'-acetamidophenyl 4-guanidinobenzoate, an experimental vaginal contraceptive and anti-HIV activity", Contraception, 1995, 51(5):319-22.	
	197	Bristow, et al., "Inhibition of HIV-1 by modification of a host membrane protease", 1995, Int Immunol, 7(2):239-49.	
	198	Bukrinskaia et al., "Inhibition of HIV reproduction in cultured cells using proteolysis inhibitors", 1989, Vopr Virusol, 34(1):53-5.	
	199	Bourinbair, et al., "Effect of serine protease inhibitor, N-alpha-tosyl-L-lysyl-chloromethyl ketone (TLCK), on cell-mediated and cell-free HIV-1 spread", Cell Immunol, 1994, 155(1):230-6.	
	200	Turpin et al., "Human immunodeficiency virus type-1 (HIV-1) replication is unaffected by human secretory leukocyte protease inhibitor", 1996, Antiviral Res, 29(2-3):269-77.	
a	201	Kennedy et al., "Submandibular salivary proteases: lack of a role in anti-HIV activity", 1998, J Dent Res, 77(7):1515-9.	

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Signature	/Kevin Weddington/ (02/15/2006)	Considered	
Oignature	/ Revin Weddington/ (02/15/2000)	Colbidered	

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Sheet	15	of	17	Attorney Docket Number	330310.00102	

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Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
U	202	Premack, B.A. et al., "Chemokine Receptors: Gateways to Inflammation and Infection", 1996, Nature Medicine 2:1174-1178.	
	203	Zhirnov O.P. et al., "Antiviral activity of proteinase inhibitors in cultured cells infected with alpha-viruses", Mol Gen Mikrobiol Virusol, 1985, (12):30-6.	
	204	Chesnokova N.B. et al., "Antiproteases in herpetic keratitis", Metab Pediatr Syst Ophthalmol, 1986;9(1):593-6.	
	Adelman S.F. et al., "Protease inhibitors suppress fibrinolytic activity of herpesvirus-transformed cells", J Gen Virol, 1982, 60(Pt 1):15-24.		
	206	Chesnokova N.B. et al., "Main proteolytic inhibitors in ocular herpes", Vopr Med Khim, 1981, 27(5):663-5.	
	207	Sharpstone D. et al., "Faecal alpha 1 antitrypsin as a marker of gastrointestinal disease in HIV antibody positive individuals", Gut, 1996, 38(2):206-10.	
	208	Patel et al., "The Role of Protease Drug During Apoptosis", 1996, FASEB J, 10(5):587-597.	
	209	Estaquier J., "Fas-mediated apoptosis of CD4+ and CD8+ T cells from human immunodeficiency virus-infected persons: differential in vitro preventive effect of cytokines and protease antagonists", 1996, Blood, 15;87(12):4959-66.	
	210	Shimizu, T. et al., "DNA Fragmentation induced by Protease Activation in P53-null Human Leukemia HL60 Cells Undergoing Apoptosis Following Treatment with the Topolsomerase I Inhibitor Camptothecin: Cell-Free System Studies", 1996, Exp Cell Res, 1:226(2):292-301.	
W	211	Glynn et al., "Apoptosis induced by HIV Infection in H9 T Cells is Blocked by ICE-Family Protease Inhibition but not by a FAS(CD95) Antagonist", 1996, J. Immunol, 1; 157(7):2754-2758.	

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STA	STATEMENT BY APPLICANT			First Named Inventor	Leland SHAPIRO	
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Sheet	16	of	17	Attorney Docket Number	330310.00102	

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10	212	Ooka, T., et al., "Protective effects of human uninary trypsin inhibitor against trypsin-induced relaxation in rat aorta", Crit care Med, 1996, 24(11): 1903-1907.	
9	213	Novradovsky, A., et al., "Endothelial Nitric Oxide Synthase as a Potential Susceptibility Gene in the Pathogenesis of Emphysema in alpha1-Antytrypsin Dieficiency", 1999, Am J Respir Cell Mol Biol, 1;20(3):441-447.	
	214	Cordiali Fei et al., "Behavior of several 'progression markers' during the HIV-Ab seroconversion period. Comparison with later stages", 1992, J Biol Regul Homeost Agents, 6(2):57-64).	
	215	Lima et al., "Mucosal injury and disruption of intestinal barrier function in HIV-infected individuals with and without diarrhea and cryptosporidiosis in northeast Brazil", 1997, Am J Gastroenterol, 92(10):1861-6.	
	216	Banfi et al., "Tumor-associated trypsin inhibitor in induced and acquired immunodeficiency. Studies on transplanted and HIV-infected patients", 1991, Scand J Clin Lab Invest 51, Suppl, 207:55-8.	
	217	Deam et al., "Alpha 1-antitrypsin phenotypes in homosexual men", 1989, Pathology, 21(2):91-2.	
	218	Pezzilli et al., "Serum pancreatic enzymes in HIV-seropositive patients", Dig Dis Sci, 1992, 37(2):286-8.	
	219	Tang et al., "Inactivation of HIV-1 by trypsin and its use in demonstrating specific virus infection of cells", 1991, J Virol Methods, 33(1-2):39-46.	
	220	Glozman, "Immunologic functions of enzyme therapy of patients with orchiepidymitis", 1990, Antibiot. Khimioter, 35(7):50-52.	
Ü	221	Franzusoff, et al., "Biochemical and genetic definition of the cellular protease required for HIV-1 gp160 processing", 1995, J Biol Chem, 270(7):3154-9).	

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l	222	Gu et al., "Furin is important but not essential for the proteolytic maturation of gp160 of HIV-1", FEBS Lett. 1995, 365(1):95-7.	
10	223	Bukrinskaia A.G., "Suppression of rotavirus SA-11 reproduction by protease inhibitors in cell culture", Vopr Virusol, 1987, 32(1):71-4.	
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